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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,568	12/05/2003	Hanns-Wolf Baenkler	STURK0007	7997

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,568	BAENKLER ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/5/03, 10/12/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Part (a) of claim 1 is indefinite since it is not clear whether each of the lipid measurement parameters A, B, C... is measured in each of the plurality of samples or whether only one of each specific lipid measurement parameter A, B, C... is measured in only one of the plurality of samples. Part (b) of claim 1 is indefinite since it is not clear whether the samples to which are added the first modulating effector or indicator substance are the same samples to which the further modulating effector is added, or whether separate samples are used in which some are combined with the first modulating effector or indicator substance and some are combined with the second further modulating effector. In other words, it is not clear whether the plurality of samples are first combined with the first modulating effector or indicator substance and then subsequently combined with the further modulating effector, or whether each of the plurality of samples is treated with either the first modulating effector/indicator substance or the second, further modulating effector, but not both. Part (c) of claim 1 is indefinite since it is not clear what represents the "one or more standard groups". Do these groups represent healthy individuals who are free of any pathological state or predisposition thereto, or do these groups represent the organism to be investigated who has had samples analyzed in the same manner at some other point in time? There is no comparative basis for what constitutes the "standard groups", and it is not clear how "standard" is defined since it can mean multiple things. See this

same problem in part (d) of claim 1. Part (e) of claim 1 is indefinite since it does not correspond to the purpose of the method as set forth in the preamble of the claim. The preamble of claim 1 recites a method for the diagnosis of a pathological state or the predisposition thereto in an organism to be investigated, and does not recite the confirmation or exclusion of risk factors. Part (e) of claim 1 is also indefinite since it is not clear how the comparison between the standardized modulation quotient profile and the standardized effector quotient profile of the organism to be investigated with these same profiles in a corresponding investigation group serves to diagnose, confirm or exclude a pathological state in the organism being investigated since part (e) does not positively recite how closely the profiles have to match one another in order to achieve a positive or negative diagnosis. In other words, part (e) does positively recite in quantitative terms how similar or different the profiles have to be in order to achieve a positive or negative diagnosis, and therefore, one or ordinary skill in the art would not be able to assess how to achieve either diagnosis without undue experimentation. See all of these same problems in claim 21.

On lines 1-2 of claim 6, the phrase "said further modulating effector used in step (a)" is indefinite since it is step (b) in claim 1 that positively recites the further modulating effector.

On line 1 of claim 9, the phrase "said intolerance" lacks antecedent basis since claim 9 depends from claim 6. In order for this phrase to have proper antecedent basis, claim 9 should depend from claim 7. On line 3 of claim 9, the phrase "said coagulation defects" lack antecedent basis for the same reason. On line 5 of claim 9, the phrase "said overcoming of infection" lacks antecedent basis for the same reason. On line 8 of claim 9, the phrase "the inflammation" lacks antecedent basis for the same reason. On lines 6-7 of claim 9, the phrase "e.g. associated with

bacterial or viral or mycotic mucositis" renders the claim indefinite because it is unclear whether the limitation(s) in the example are part of the claimed invention. See MPEP § 2173.05(d).

Claim 16 is indefinite since it is not clear to whom the medicament is administered. The same organism to be investigated as recited in claim 1? It is also not clear that the administration of the medicament is the therapy that is being monitored in the method.

Claim 17 is indefinite since it is not clear how the method is used to find an active substance for the treatment of pathological states using the method of claim 1 when in the method of claim 1, it is not definitive that the organism being investigated has a pathological state with certainty. Therefore, if the organism being investigated in the method of claim 1 is determined not to have a pathological state, it will not be possible to evaluate a substance for the treatment a pathological state.

Claim 18 is indefinite since it is not clear that the organism being investigated in the method of claim 1 is the same organism/person that is administered the substance that induces a pathological state in claim 18. In other word, it is not clear to whom the substance that causes a pathological state is administered.

On lines 6 and 9-10 of claim 20, the phrase "the phosphatidylinositol phosphates" lacks antecedent basis and should be changed to –phosphatidylinositol phosphates--.

In claim 21, the parts (e), (f), (g) and (h) should be relabeled as parts (a), (b), (c) and (d) since claim 21 is an independent claim, and is not dependent on claim 1. In part (e) of claim 21, the phrase "from an organism" should be changed to –from an organism to be investigated—in order to correspond with this same phrase used several times later in the claim. Part (f) of claim 21 is indefinite since it is not clear that the different means for measuring serve to measure the

recited parameters in the sample from the organism provided in part (e). It is not clear what the different recited parameters recited in part (f) are measured in.. See all of the same problems mentioned above for independent claim 1 in claim 21.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 and 21 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action since none of the prior art of record teaches or fairly suggests a method and apparatus for diagnosing a pathological state or the predisposition thereto in an organism by providing a sample from the organism, measuring a plurality of zero values for multiple different lipid parameters A, B, C... in the absence of a modulating effector in the sample, measuring a plurality of indicator values Amax, Bmax, Cmax... for the multiple lipid parameters in the sample in the presence of a first modulating effector or indicator substance, measuring a plurality of values for further modulation A2, B2, C2... for the multiple lipid parameters in the sample in the presence of a second, further modulating effector, calculating a plurality of quotients Amax/Ao, A2/Ao, Bmax/Bo, B2/Bo, Cmax/Co, C2/Co... and dividing the quotients by the corresponding values of one or more standard groups to yield standardized modulation quotients that in total form a standardized

modulation quotient profile, calculating a plurality of quotients Ao/Bo, Bo/Ao...etc. in any combination, Amax/Bmax, Cmax, Amax, ... etc. in any combination and A2/B2, B2/C2...etc. in any combination and dividing the quotients by a plurality of corresponding values obtained for one or more standard groups to yield standardized effector quotients that in total form a standardized effector quotient profile for the organism being investigated, and diagnosing a pathological state in the organism by comparing the standardized modulation quotient profile and the standardized effector quotient profile of the organism being investigated with that of a corresponding investigation group in which the pathological state is present. In particular, none of the prior art of record teaches or fairly suggests the steps of calculating the quotients of the different lipid measurement parameters, and dividing the quotients by the corresponding values of one or more standard groups, resulting in a standardized modulation quotient profile and a standardized effector quotient profile for the organism being investigated, and comparing both profiles to similar profiles in a corresponding investigation group having a pathological state in order to diagnose the pathological state in the organism under investigation.

5. Claims 2-20 and 22-23 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the same reasons as given above.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

April 12, 2007

Maureen M. Wallenhorst

MAUREEN M. WALLENHORST
PRIMARY EXAMINER
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